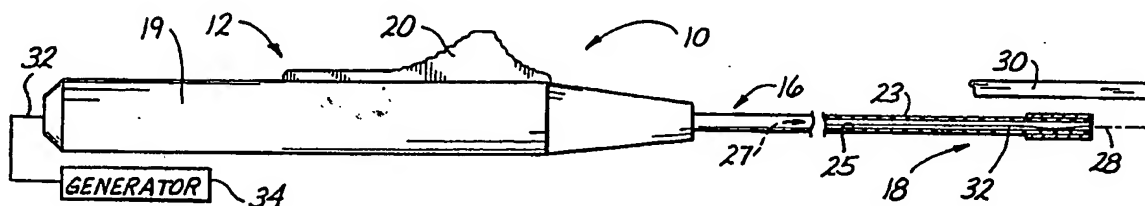




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(54) Title: ARTICULATING TISSUE CUTTER ASSEMBLY



(57) Abstract

A surgical cutter (10) includes a cannula (16) having walls (21) defining a lumen (27) and cutting means (32) disposed in the lumen (27) and being movable from a retracted position wherein the cutting means (32) is removed from the tissue and a deployed position wherein the cutting means (32) contacts the tissue. The cutting means (32) is biased toward the deployed position but means (20) is provided for releasably retaining the cutting means in the retracted position. An associated method includes the steps of releasing the retaining means to enable the cutting means to automatically move to the deployed position.

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ARTICULATING TISSUE CUTTER ASSEMBLY**BACKGROUND OF THE INVENTION****Field of the Invention**

This invention relates generally to radio frequency cutters and more specifically to radio frequency cutters which are adapted for use in cutting the tissue of a patient.

Discussion of Prior Art

10 With the increasing interest in performing surgeries with less invasive techniques, operations employing endoscopes are becoming quite common. An endoscope, sometimes referred to merely as a "scope", is an instrument which can be inserted through a small hole or passage to reach an operative site within the body of the patient. The endoscope includes fiber optic mechanisms for visualization and is commonly provided with a working channel which is adapted to receive various instruments capable of performing surgical functions at the operative site. One such instrument is a radio frequency cutter which includes a passive electrode, and an active electrode which is disposed at the operative site. By energizing the active electrode with a radio frequency signal, tissue in proximity to the electrode can be cut, cauterized or fulgurated.

Radio frequency cutting instruments of the past have included active electrodes in the form of wires and spoons which have been deployable from an elongate tube of the

cutter. Generally these electrodes have been deployed along the axis of the tube so that any cutting of tissue proximal to the tube has required that the entire cutter be tilted to bring the tissue into proximity with the electrode.

In some cases, it has been desirable to cut the wall of a body passage or tube. In one attempt to produce this result, a cutter has been provided with an active electrode which includes a wire bent laterally to extend beyond the wall of the cutter tube. With this configuration, insertion techniques require that this cutter be used solely with an endoscope and that the lateral extension of the wire beyond the cutter tube be limited to the diameter of the endoscope. Furthermore, the entire cutter assembly must be loaded into the front of the endoscope where the wire electrode sits against the distal face of the scope. After the scope is inserted, it is withdrawn slightly leaving the wire in contact with the passage wall.

20

An intolerable aspect of this apparatus and procedure requires that the entire endoscope be withdrawn from the body in order to remove the cutter from the front of the instrument. This is the only way to clear the working channel of the endoscope in order to permit other instruments to be used. Of course once the endoscope is removed, it must be reinserted in order to gain access to the operative site.

25

SUMMARY OF THE INVENTION

In accordance with the present invention a tissue cutter assembly is provided which overcomes these disadvantages of the prior art. The cutter assembly can be used independently of an endoscope or can be back-loaded

30

into an endoscope. This feature is particularly desirable since it enables the cutter to be operatively disposed and removed without requiring removal of the endoscope.

5 The cutter assembly includes an elongate tube and an
radio frequency electrode which can be articulated relative
to the tube between a retracted position and a deployed
position. In the retracted position, the electrode can be
fully contained within the tube thereby permitting the
10 cutter to be inserted and removed through the back of the
scope. In the deployed position, the electrode
automatically seeks a memory shape having a preformed
configuration. In one embodiment, this configuration may
take the shape of a wire having a 90° bend and an end which
15 extends laterally beyond the wall of the tube. With the
memory characteristics associated with the electrode, many
different configurations will be of interest.

 In one aspect of the invention, a surgical cutter is
20 adapted to incise body tissue and includes a cannula having
walls defining a lumen which extends along an elongate axis
from a proximal end of the cannula to a distal end of the
cannula. A handle coupled to the proximal end is operable
to move the distal end of the cannula into proximity to the
25 body tissue to be cut. Cutting means disposed in the lumen
is movable between a retracted position wherein the cutting
means is spaced from the tissue, and a deployed position
wherein the cutting means contacts the tissue. This
cutting means is biased toward the deployed position, but
30 articulating means is provided and movable relative to the
handle for releasibly retaining the cutting means in the
retracted position.

 Another aspect of the invention includes a method for
35 cutting body tissue which comprises the steps of providing

such a surgical cutter, moving the cannula of the cutter to the operative site, releasing the retaining means to enable the cutting means to automatically move to the deployed position, activating the cutting means, and moving the
5 activated cutting means along the tissue to cut the tissue at the operative site.

These and other features and advantages of the invention will become more apparent with a description of
10 preferred embodiments and reference to the associated drawings.

DESCRIPTION OF THE DRAWINGS

15

Fig. 1 is a side elevation view of one embodiment of a cutter assembly of the present invention showing an radio frequency electrode in a relatively retracted position;

20

Fig. 2 is an axial cross-section view of the cutter assembly illustrated in Fig. 1, the radio frequency electrode being shown in a relatively deployed position;

25

Fig. 3 is a cross-section view taken along lines 3 - 3 of Fig. 2;

Fig. 4 is a cross-section view taken along lines 4 - 4 of Fig. 2;

30

Fig. 5 is an axial cross-section view similar to Fig. 2 and illustrating another embodiment of the cutter assembly of the present invention;

35

Fig. 6 is a cross-section view taken along lines 6 - 6 of Fig. 5;

Fig. 7 is a perspective view of a pyelotomy procedure involving the cutter assembly of the present invention;

Fig. 8 is an axial cross-section view of a ureter
5 showing a cutter electrode in the retracted position;

Fig. 9 is an axial cross-section view of the ureter showing the electrode in the deployed position;

10 Fig. 10 is an axial cross-section view of an additional embodiment of the cutter electrode associated with the present invention;

15 Fig. 11 is a side view taken along lines 11 - 11 of Fig. 10;

Fig. 12 is an axial cross-section view of a further embodiment of an electrode configuration associated with the present invention;
20

Fig. 13 is an axial cross-section view of a loop configuration associated with the electrode of the present invention;

25 Fig. 14 - 16 is a series of views showing an electrode with a plurality of memory configurations;

Fig. 14 is an axial cross-section view showing the electrode in the retracted position;
30

Fig. 15 is an axial cross-section view showing the electrode in a partially deployed position; and

35 Fig. 16 is an axial cross-section view showing the electrode in a fully deployed position.

DESCRIPTION OF PREFERRED EMBODIMENTS

5 A cutter assembly is illustrated in Figure 1 and designated generally by the reference numeral 10. The cutter has a handle 12 disposed at a proximal end 14 of the assembly 10, and a probe 16 extending from the handle 12 to a distal end 18 of the assembly 10. The handle 12 includes a housing 19 and finger tab 20 which is movable relative to
10 the housing 19, for example by sliding. The probe 16 is characterized by a cylindrical wall 21 having an outer surface 23 and an inner surface 25 which defines a lumen 27 along an axis 28.

15 This cutter assembly 10 is adapted to cut body tissue, which is shown schematically in Figure 1 and designated by the reference numeral 30. It may also be adapted to coagulate blood or fulgurate the tissue 30 or perform any of the other functions (collectively referred to herein as
20 cutting) normally associated with radio frequency cutters. This cutting is accomplished by an electrode 31 which takes the form of a wire 32 in the embodiment of Figure 1. This wire 32 extends through the lumen 27 of the probe 16 and through the handle 12 to exit the cutter assembly 10 at the
25 proximal end 14 where it is connected to a radio frequency generator 34. In an embodiment wherein the wire 32 has an outside diameter of .010 inches, the lumen 27 may have an inside diameter of .019 inches.

30 In general, radio frequency cutting systems include two electrodes, an active electrode, such as the wire 32, and a passive electrode. In monopolar systems, the passive electrode is provided in the form of a dispersion plate having a large surface area which contacts the tissue 30 at
35 some location distant from the operative site. In such a

system, the radio frequency current from the generator 34 flows from the active electrode, such as the wire 32, to the dispersion plate. A high current density causes the tissue 30 to vaporize in proximity to the tip of the wire 32. The best cutting seems to occur when the wire 32 is in close proximity to, but does not actually touch, the tissue 30. As used herein, the word "contact" includes their closely proximate relationship between the wire 32 and the tissue 30.

10

In bipolar systems, both the active and passive electrodes are provided at the operative site. Current from the generator 34 flows between these two electrodes vaporizing the tissue 30 in this region. These concepts relating to radio frequency cutting, coagulation and fulguration are disclosed in a Valleylab Training Manual entitled "Introduction to Electrosurgery" which is incorporated herein by reference.

20

The configuration of the wire 32 at the distal end 18 of the cutter 10 is of particular interest to the present invention. It is advantageous to have the wire 32 configured so that in a relatively deployed state, it extends from the distal end of the probe 16 and laterally of the axis 28 beyond the outer surface 23 of the wall 21. In this deployed position, best illustrated in Figure 2, the wire 32 can contact the tissue 30. Then, when the generator 34 is activated and the wire 32 begins cutting, the entire cutter assembly 10 can be moved axially to cut the tissue 30.

30

While this deployed configuration may be preferable for cutting, it is totally inappropriate for positioning the cutter assembly 10 through the working channel of an endoscope (not shown) or for otherwise inserting the probe

35

16 into a tubular body passage. For this reason, it is desirable that the wire 32 also be able to achieve a retracted position, best illustrated in Figure 1, where the wire 32 is disposed at least partially in the lumen 27 and has a generally straight configuration. As used herein, the word "retracted" includes any disposition of the electrode 31 relative to the probe 16 which would enable the probe 16 to be inserted into a conduit without the electrode 31 contacting the conduit. Such a conduit may include an introducer, a trocar, the working channel of an endoscope, or a body conduit.

In a preferred embodiment, the wire 32 has pseudoelastic characteristics commonly referred to as a memory. Thus in a preferred embodiment, the wire 32 is formed with a memory or bias for the deployed state illustrated in Figure 2. However, when the wire 32 is moved into the lumen 27, it straightens to the retracted state illustrated in Figure 1.

In this retracted state, the cutter assembly 10 can be inserted and positioned at the operative site. Then the wire 32 can be relatively deployed to achieve its memory state, such as that illustrated in Figure 2. After the wire 32 has been activated and the cut has been completed, the wire 32 can be relatively retracted back into the lumen 27 and the entire cutter assembly removed from the body. Importantly, if this cutting action is accomplished through the working channel of an endoscope, the entire cutting operation can be completed with the endoscope left in place.

The mechanism for moving the wire 32 between the retracted state and the deployed state requires only that the distal end of the wire 32 be movable relative to the

distal end of the probe 16. In the embodiment of Figure 2, this relative movement of the probe 16 and wire 32 is accomplished by fixing the wire 32 to the housing 19 and fixing the probe 16 to the movable finger tab 20. Then by
5 moving the tab 20 relative to the housing 19, the distal end of the probe 16 moves relative to the distal end of the wire 32.

In the illustrated embodiment, the wire 32 is fixed to
10 the housing 19 by a sleeve 41 which is crimped, adhered or otherwise bonded to the wire 32. This sleeve 41 includes portions which define a flange 43 that is received in a recess 45 of the housing 19. With the sleeve 41 bonded to the wire 32 and held in the recess 45 of the housing 19,
15 the wire 32 has a fixed relationship with the handle 12.

In the embodiment of Figure 2, the probe 16 has a fixed relationship with the finger tab 20 which is movable relative to the housing 19 and the wire 32. The finger tab
20 20 includes an exterior portion 50 which is connected through a neck 52 to an interior portion 54 of the tab 20. The neck 52 extends through a slot 56 in the housing 19 but has an axial dimension less than that of the slot 56 so that the tab 20 is slidable axially relative to the housing
25 19.

At the distal end of the handle 12, the housing 19 narrows to form supporting shoulders 61 for the probe 16. In this embodiment, the shoulders 61 are not attached to
30 the probe 16, but are slidable on the probe 16 as it moves relative to the handle 12.

The mechanism for attaching the probe 16 to the finger tab 20 includes a sleeve 70 which is bonded, or otherwise
35 fixed to the proximal end of the probe 16. This sleeve is

disposed between a pair of radially extending flanges 72 and 74 which form part of the interior portion 54 of the tab 20. The distal flange 74 is provided with an aperture which is sufficiently large to receive the outer diameter of the probe 16. A similar aperture in the proximal flange 72 is sized to pass only the wire 32. These dimensions permit the wire 32, probe 16 and sleeve 70 to be snap-fit into the flanges 72, 74 through respective side openings, such as the opening 76 which is best shown in Figure 3. Since the sleeve 70 has an outer dimension greater than that of the probe 16, it will not pass distally of the flange 74. And since the probe 16 and sleeve 70 have a dimension greater than the hole in the flange 72, they cannot pass proximally of the flange 72. Thus the sleeve 70 and associated flanges 72, 74 provide means for maintaining the finger tab 20 and the probe 16 in a fixed relationship.

It is particularly desirable that the operator of the cutter assembly 10 be able to view the handle 12 and determine the deployed position of the wire 32. This is accomplished in a preferred embodiment by providing a band 83 over the distal end of the probe 16 and crimping the band 83 slightly. This provides the lumen 27 with the configuration of an oval having a major axis 85 and a minor axis 87 as best illustrated in Figure 4. This oval configuration of the lumen 27 at the distal end of the probe causes the wire 32 to deploy along the major axis 85. This axis 85 can be maintained in a fixed relationship with the handle 12 by providing the sleeve 70 with a non-rotatable relationship to the finger tab 20. In a preferred embodiment the sleeve 70 is octagonal in cross-section and provides a flat surface 90 which abuts the interior portions 54 of the tab 20 thereby preventing rotation of the sleeve 70, probe 16, and major axis 85. In

this manner, the sleeve 70 and the band 83 provide means for determining the deployed position of the wire 32 relative to the handle 12.

5 In a particular embodiment, the interior portions 54 may include an extension 88 which forms at least one projection 89. This projection 89 is adapted to register with at least one of a series of teeth 90 which are formed in the opposing surface of the housing 19. In such an
10 embodiment, each of the teeth 90 forms a detent for registration with the projection 89 at a different axial position of the finger tab 20 relative to the housing 19. This series of detents are particularly helpful in controlling the exact configuration of the electrode 34 as
15 it deploys from the probe 16.

 In a further embodiment of the invention, the wire 32 is moved relative to the probe 16 by fixing the wire to the finger tab 20 while retaining the probe 16 in a fixed
20 relationship with the housing 12. In this embodiment, illustrated in Figure 3, structural elements which are similar to those previously described are designated with the same reference numeral followed by the lower case "a".

25 In the embodiment of Figure 5, the probe 16a is fixed to the housing 19a by adhering, bonding or otherwise attaching the shoulders 61a to the outer surface 23a of the probe 16a. The finger tab 20a is fixed to the wire 32a by providing the octagonal sleeve 70a with axial projections
30 94 and 96. The sleeve 70a is preferably formed of stainless steel which permits the projections 94 and 96 to be crimped to the wire 32a. These crimped projections 94 and 96 are relatively small in diameter compared to the remainder of the sleeve 70a. The projections 94, 96 are
35 adapted to be received in the holes of the respective

flanges 72a and 74a with the remainder of the sleeve 70a disposed therebetween. In this manner, the sleeve 70a and associated flanges 72a, 74a provide means for fixing the wire 32a to the tab 20a. Thus, the wire 32a is attached to the finger tab 20a but is otherwise movable within the handle 12a. By thus fixing the probe 16a to the housing 19a and fixing the wire 32a to the finger tab 20a, movement of the tab 20a relative to the housing 19a results in relative movement of the probe 16a and wire 32a.

10

In order to maintain the orientation of the deployed wire 32a relative to the handle 12a, again it is desirable that the sleeve 70a be provided with a flat surface in abutting relationship with the interior portions 54a of the tab 20a. This structural characteristic, which prevents the wire 32a from rotating relative to the handle 20a, is best illustrated in Figure 6.

Operation of the cutter assembly 10 can be better understood with reference to certain surgical procedures such as that illustrated in Figure 7. In this figure, a pair of kidneys are designated by the respective reference numerals 101 and 103. Each of the kidneys 101, 103 is associated with a ureter such as that designated by the reference numeral 107. The ureter 107 is a duct which conducts urine from the kidney to the bladder of a patient. It is susceptible to strictures which are generally areas of constriction that are caused by birth defects, injuries, or passing stones. The procedure for opening a stricture in order to provide a more patent flow path within the ureter 107, requires the surgeon to cut the wall of the ureter axially along the stricture, thereby creating a greater circumference for the ureter 107. Then, a stent (not shown) can be inserted to maintain the enlarged

channel. Healing occurs around the stent and over the incision leaving the ureter 107 with an enlarged flow path.

5 In accordance with the present invention, the cutter assembly 10 with the wire 32 in its retracted state can be inserted into the ureter 107 up to a particular stricture of interest such as that designated by the reference numeral 110. By manipulating the handle 12, the probe 16 can be advanced through the ureter 107 until the distal end 10 18 is positioned beyond the stricture 110. At this point the finger tab 20 can be operated to deploy the electrode or wire 32a. With the memory characteristics previously discussed, movement of the wire 32 along the axis 28 of the probe 16 will enable the distal end of the wire 32 to 15 extend laterally to the deployed position. When the electrode or wire 32 is activated, it will cut its way through the wall of the ureter 107. Then as the cutter 10 is withdrawn, the wire 32 will automatically produce an axial cut along the wall of the ureter 107.

20

In this particular embodiment, the electrode 31 at the distal end of the wire 32 extends laterally along an axis 114 in its deployed position. The angle separating the axis 28 of the probe 16 and the axis 114 of the electrode 25 34 is designated α in Figure 8. For this particular procedure, it is particularly advantageous if this angle α is in a range between 70° and 110° . In a preferred embodiment, the angle α is 90° .

30 It will be apparent that the configuration of the wire 32 in the deployed state is limited only by the ability of the wire 32 to maintain the desired memory characteristics when the wire 32 is in the retracted state. In a particular procedure which involves severing a length of 35 tissue, the electrode 31 may be provided with the memory

characteristics of a hook or J-shape, as illustrated in Figure 10. For example, it may be desirable in a cholangiography procedure to entirely sever the cystic duct 118. By positioning the probe 16 adjacent to the duct 118 and deploying the wire 32, the J-shaped electrode 34 will automatically form around the duct 118. Then, by activating the electrode 34 and moving the cutter 10 proximally, the duct 118 will be severed.

For the purposes of cutting tissue, the monopolar configuration of the wire 32 may be preferred. However, it is generally believed that coagulation and fulguration can best be achieved with a bipolar electrode 34. The cross-section of Figure 10 illustrates such an electrode which includes an active portion 31c and a passive portion 31d. These portions 31c and 31d are separated by an insulator 121. When moved into proximity to the duct 118, the current flowing into the active portion 31c passes through the duct 118 to the passive electrode 31d, thereby severing the duct 118.

A bipolar electrode configuration may also take the form illustrated in Figure 11 which includes an active electrode 34 and a passive electrode 125 which is independently deployable. If only monopolar cutting were desired, the active electrode 34 could be used with a dispersion plate (not shown). However, if coagulation or fulguration were desired, the passive electrode 125 could be deployed into proximity with the active electrode 34 to provide for bipolar operation.

In a further embodiment of the invention, two active electrodes could be provided and commonly deployed to extend in opposite directions. Such a device would be

particularly advantageous in a procedure for deactivating vein valves.

One of the many electrode configurations which can be
5 achieved with the present invention might include a loop
127 as illustrated in Figure 12. By deploying the
electrode 34 the loop 127 would automatically form for
operative disposition around an object to be removed. In
this manner, the electrode 34 would function as a snare
10 thereby providing for removal of an object such as a polyp.

With reference to Figures 13 - 15, it will be apparent
that the memory characteristics of the wire 32 can be
provided at different locations along the wire. Thus
15 memory characteristics could be provided at a point 130
along the wire 32 which would provide for a positive 90°
bend for the electrode 34. In the same wire 32, but at a
more proximal location, memory characteristics could be
provided at a point 132 which would provide the electrode
20 with a negative angle such as 30°. Given these
characteristics, when the wire 32 is initially deployed,
and only the point 130 extends beyond the end of the probe
16, the electrode 34 would have the configuration
illustrated in Figure 14. However, when the wire 32 is
25 further deployed and the point 132 clears the distal end of
the probe 16, the electrode 34 would have the configuration
illustrated in Figure 15.

In a preferred embodiment, the handle 12 is formed
30 from polycarbonate. The probe 16 is formed from a
polyamide material and provided with a wall thickness of
.003 inches. The wire 32 is formed from an alloy of nickel
and titanium and is provided with a coating of Teflon®, a
trademark of E. I. DuPont de Nemours. In a preferred
35 embodiment, the wire has superelastic characteristics and

is of the type distributed by Shape Memory Applications, Inc. under model F2265-1.

Although the invention has been described with
5 reference to a certain configurations for the electrode 34,
it will be apparent that many other shapes and forms can be
achieved relying on the memory characteristics of the wire
32. Similarly, there may be other embodiments for moving
the wire between a retracted position and a deployed
10 position. Articulating mechanisms other than a finger tab
may offer certain advantages for a particular embodiment.

Given the wide variety of variations within the
invention, one should not determine the breadth of the
15 concept with reference merely to the described embodiments
and illustrations. Rather, the scope of the invention
should be ascertained only with reference to the following
claims.

CLAIMS

ARTICULATING TISSUE CUTTER ASSEMBLY

1. A surgical cutter adapted to incise body tissue, comprising:

a cannula having walls defining a lumen which extends along an elongate axis from a proximal end of the cannula
5 to a distal end of the cannula;

a handle coupled to the proximal end of the cannula and operable to move the distal end of the cannula into proximity to the body tissue to be cut;

cutting means disposed in the lumen of the cannula and
10 being movable between a retracted position wherein the cutting means is spaced from the tissue, and a deployed position wherein the cutting means contacts the tissue;

the cutting means being biased toward the deployed position; and

15 means movable relative to the handle for releasably retaining the cutting means in the retracted position.

2. The surgical cutter recited in Claim 1 wherein the cutting means includes a wire formed from an alloy which provides the wire with memory characteristics for seeking the deployed position.

3. The surgical cutter recited in Claim 2 wherein the wire has a distal end section and the retaining means comprises a finger tab movable on the housing and engaging the wire for movement of the wire from the deployed
5 position wherein the distal end section of the wire extends from the distal end of the tube, to the retracted position wherein the distal end section of the wire is disposed in the lumen of the tube.

4. The surgical cutter recited in Claim 2 wherein the wire is adapted to receive a radio frequency signal for cutting the tissue.

5. The surgical cutter recited in Claim 1 wherein:
the body tissue forms a wall of a conduit;
the tube is adapted to be moved along the conduit with
the cutting means in the deployed position; whereby
5 the wall tissue is cut axially by the wire to open the conduit.

6. The surgical cutter recited in Claim 2 wherein the alloy forming the wire includes nickel and titanium.

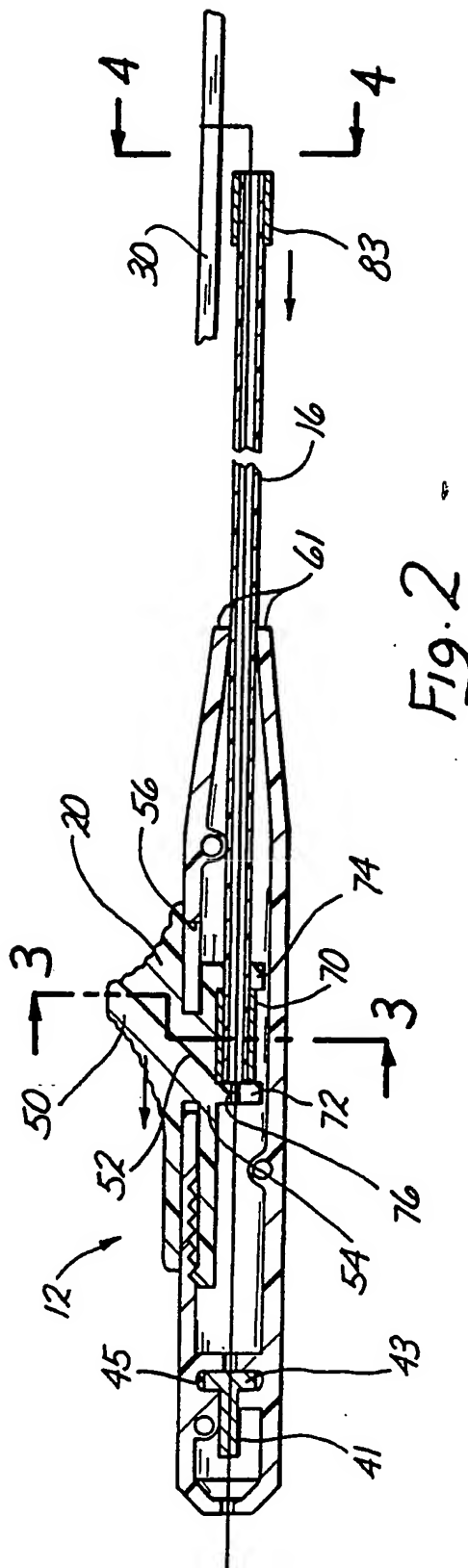
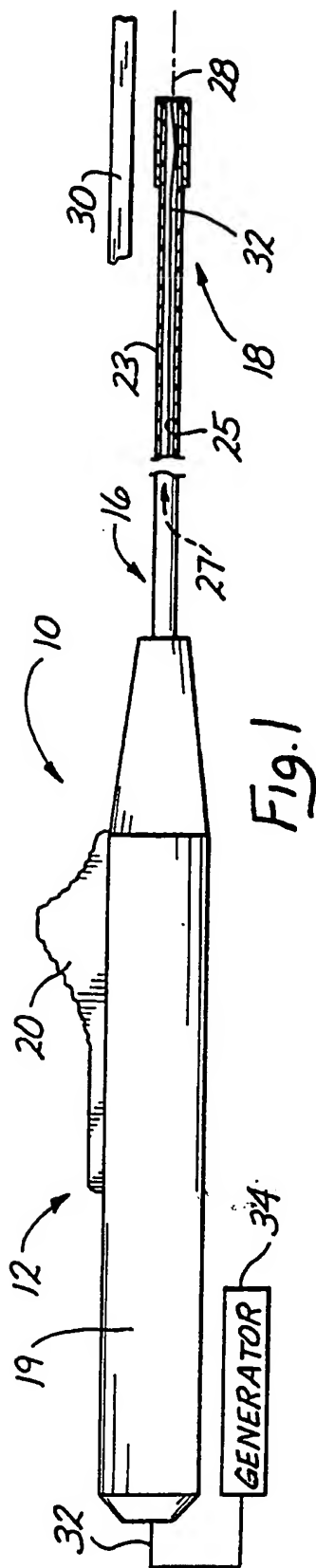
7. A method for cutting body tissue at an operative site, comprising the steps of:

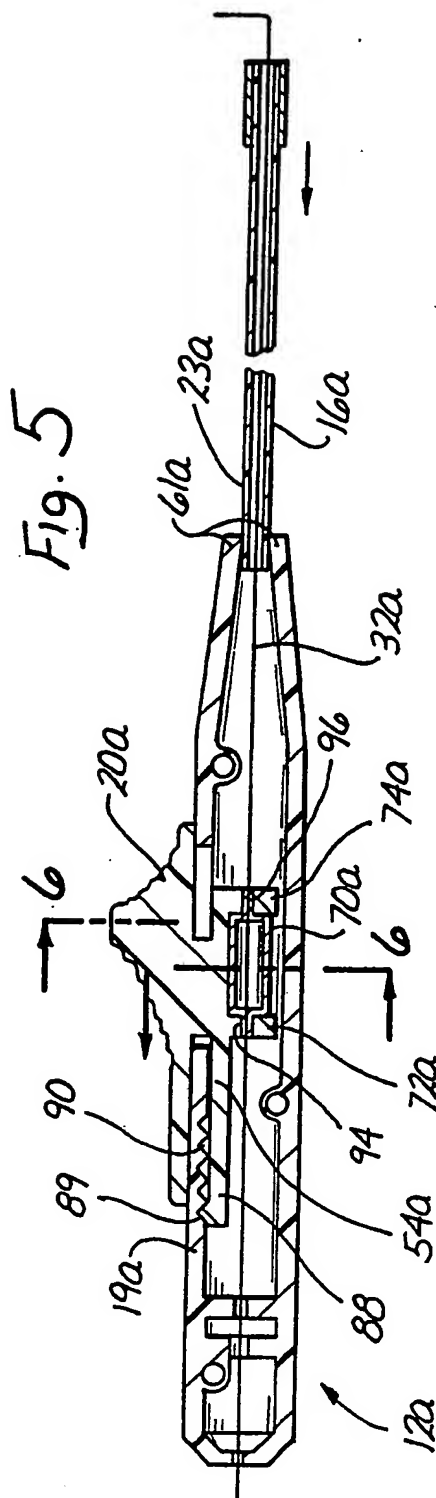
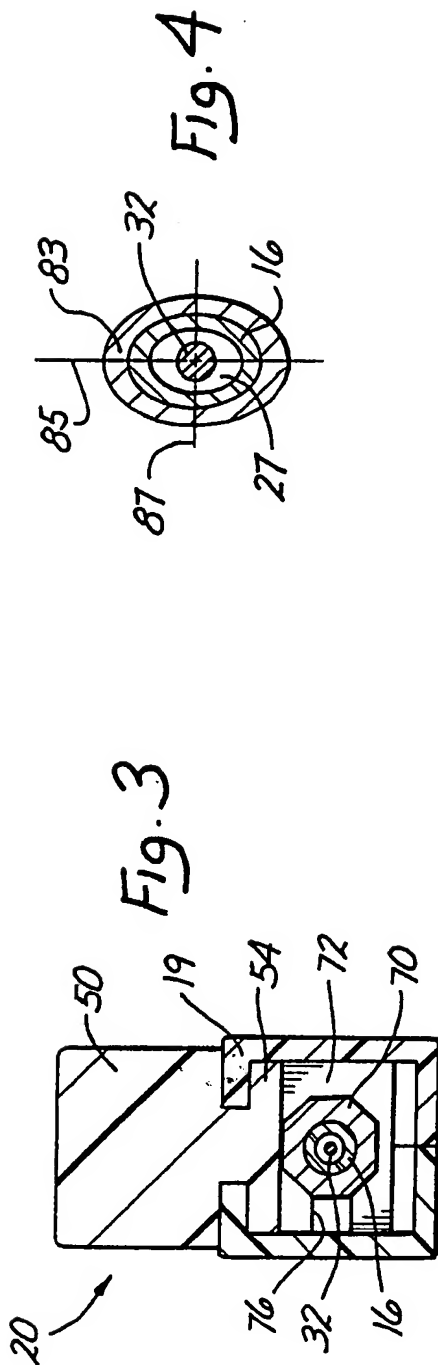
- 5 providing a surgical cutter comprising a cannula having walls defining a lumen which extends along an elongate axis from a proximal end of the cannula to a distal end of the cannula, cutting means disposed in the cannula and automatically movable from a retracted position to a deployed position in contact with the tissue, and means for releasably retaining the cutting means in the
- 10 retracted position;
- moving the cannula of the surgical cutter to the operative site;
- releasing the retaining means to enable the cutting means to automatically move to the deployed position at the
- 15 operative site;
- activating the cutting means; and
- moving the activated cutting means along the tissue to cut the tissue at the operative site.

8. The method recited in Claim 7 wherein during the activating step the method further comprises the step of introducing a radio frequency signal to the cutting means to cut the tissue.

9. The method recited in Claim 7 wherein the body tissue forms the wall of a body conduit and the method further comprises the step of inserting the cannula into the body conduit.

10. The method recited in Claim 9 wherein during the second moving step the method comprises the step of withdrawing the cannula through the body conduit to cut the wall of the conduit.





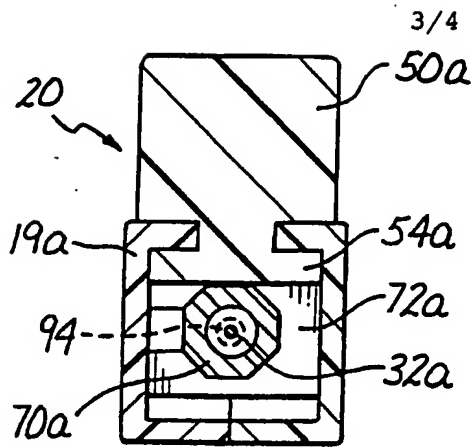


Fig. 6

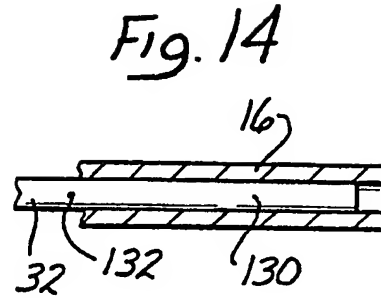


Fig. 14

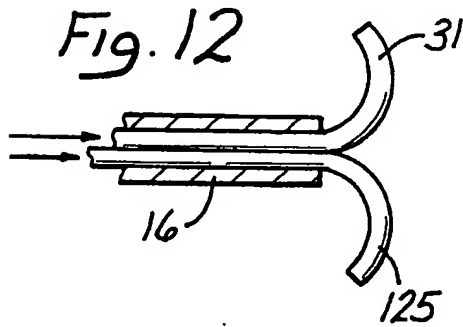


Fig. 12

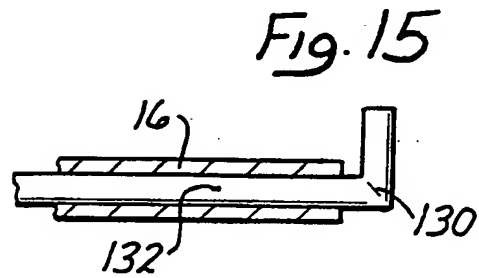


Fig. 15

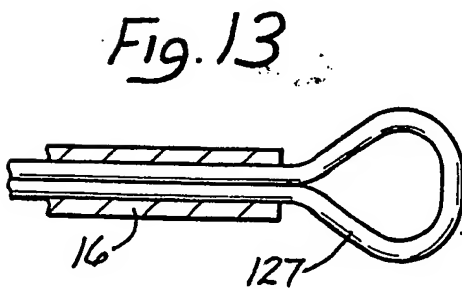


Fig. 13

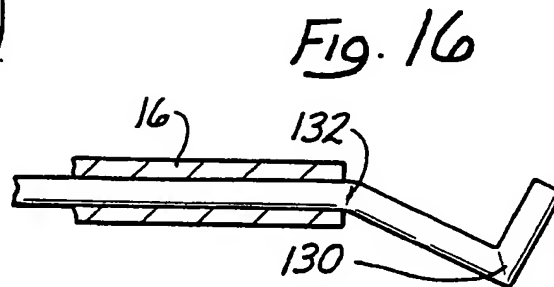
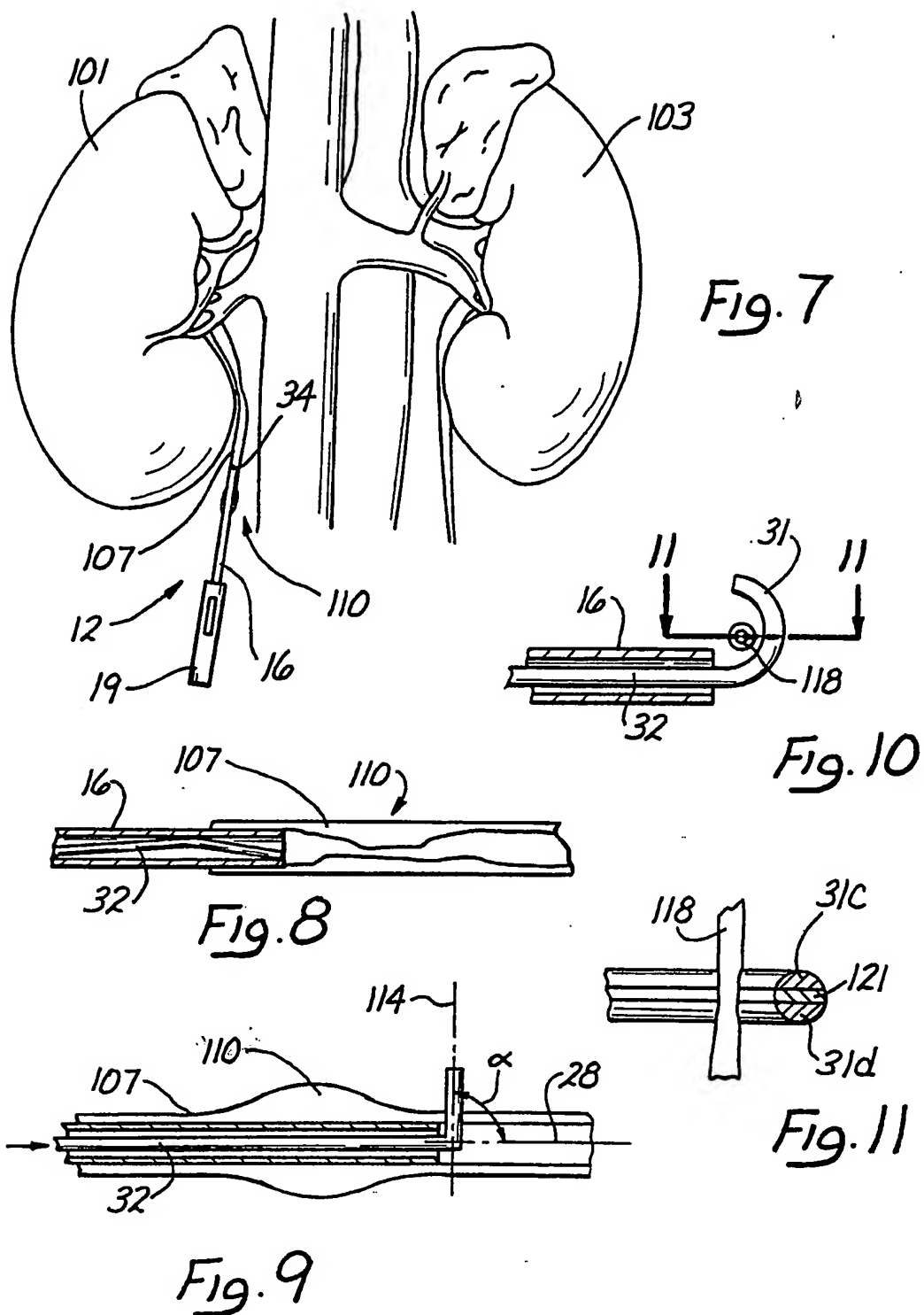


Fig. 16



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US92/04283

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 17/36

US CL :606/47

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/41,42,44,45,46,49,50

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
<u>X</u> Y	US,A, 3,805,791 (SEUBERTH ET AL.) 23 April 1974, See entire document.	1,2,4,5 & <u>7-10</u> 3,6
Y	US, A, 4,811,733 (BORSANYI ET AL.) 14 March 1989, See entire document.	1-10
Y	US, A, 4,608,986 (BERANEK ET AL.) 02 September 1986, column 4 lines 25 and 50.	6
Y	US, A, 4,202,338 (BITROLF) 13 May 1980, See entire document.	1-10
Y	WO, A, WO86/05379 (BORSANYI ET AL.) 25 September 1986, See entire document.	1-10
A	US, A, 5,009,656 (REIMELS) 23 April 1991, See entire 1991, See entire document.	1-10

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:	*T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be part of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

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